



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 814

[Docket No. FDA-2017-N-0011]

Humanitarian Use Devices; 21st Century Cures Act; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending regulations to reflect changes recently enacted into law by the 21st Century Cures Act. Specifically, certain requirements related to humanitarian device exemptions (HDEs) and institutional review boards (IRBs) for devices have changed. This action is being taken to align the regulations with the Federal Food, Drug, and Cosmetic Act (the FD&C Act) as amended.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Ian Ostermiller, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5515, Silver Spring, MD 20993-0002, 301-796-5678.

SUPPLEMENTARY INFORMATION: On December 13, 2016, the 21st Century Cures Act (Pub. L. 114-255) was signed into law, amending certain provisions of the FD&C Act. FDA is updating regulations to reflect some of those changes that are now in effect. Specifically, section 3052 of the 21st Century Cures Act amended section 520(m) of the FD&C Act to allow for HDE approval for devices that, among other things, treat or diagnose a disease or condition

that affects “not more than 8,000” individuals in the United States; this threshold had been “fewer than 4,000” individuals in the United States (amending 21 U.S.C. 360j(m), passim). This final rule amends part 814 (21 CFR part 814) in several places to accurately reflect the threshold recently enacted into law.

In addition, section 3056 of the 21st Century Cures Act amended section 520 of the FD&C Act to remove the requirement for institutional review committees, i.e., IRBs, for devices to be “local”, (amending 21 U.S.C. 360j, passim). This final rule amends 21 CFR 814.124(a), “IRB approval”, to remove the term “local” and related language in order to accurately reflect the requirements recently enacted into law.

FDA finds good cause for issuing this amendment as a final rule without notice and comment because this amendment only updates the implementing regulation to restate the statute in light of amendments recently enacted into law (see 5 U.S.C. 553(b)(B), relating to notice and comment procedures): “[W]hen regulations merely restate the statute they implement, notice-and-comment procedures are unnecessary”. Gray Panthers Advocacy Committee v. Sullivan, 936 F.2d 1284, 1291 (D.C. Cir. 1991); see also Komjathy v. Nat. Trans. Safety Bd., 832 F.2d 1294, 1296 (D.C. Cir. 1987) (when a rule “does no more than repeat, virtually verbatim, the statutory grant of authority”, notice-and-comment procedures are not required). Therefore, we are issuing these amendments as a final rule, and publication of this document constitutes final action on this change under the Administrative Procedure Act (APA) (5 U.S.C. 553).

In addition, FDA finds good cause for these amendments to become effective on the date of publication of this action. The APA allows an effective date less than 30 days after publication as “provided by the agency for good cause found and published with the rule” (5 U.S.C. 553(d)(3)). A delayed effective date is unnecessary in this case because the new

requirements are already effective as a matter of law. Furthermore, this rule does not establish additional regulatory obligations or impose additional burden on regulated entities. As a result, affected parties do not need time to prepare before the rule takes effect. Therefore, FDA finds good cause for these amendments to become effective on the date of publication of this action.

List of Subjects in 21 CFR Part 814

Administrative practice and procedure, Confidential business information, Medical devices, Medical research, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 814 is amended as follows:

PART 814--PREMARKET APPROVAL OF MEDICAL DEVICES

1. The authority citation for part 814 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 353, 360, 360c-360j, 371, 372, 373, 374, 375, 379, 379e, 381.

§ 814.3 [Amended]

2. Amend § 814.3(n) by removing the words “fewer than 4,000” and adding in their place the words “not more than 8,000”.

§ 814.100 [Amended]

3. Amend § 814.100(b) introductory text by removing the words “fewer than 4,000” and adding in their place the words “not more than 8,000”.

§ 814.102 [Amended]

4. Amend § 814.102 as follows:
 - a. In paragraph (a)(5), remove the words “fewer than 4,000” in both occurrences and add in their places the words “not more than 8,000” for both occurrences;

b. In paragraph (b)(3)(i), remove the words “fewer than 4,000” and add in their place the words “not more than 8,000”; and

c. In paragraph (b)(3)(ii), remove the words “4,000 or more” and add in their place the words “more than 8,000”.

5. In § 814.124, revise paragraph (a) to read as follows:

§ 814.124 Institutional Review Board requirements.

(a) IRB approval. The HDE holder is responsible for ensuring that a HUD approved under this subpart is administered only in facilities having oversight by an Institutional Review Board (IRB) constituted and acting pursuant to part 56 of this chapter, including continuing review of use of the device. In addition, a HUD may be administered only if such use has been approved by an IRB. If, however, a physician in an emergency situation determines that approval from an IRB cannot be obtained in time to prevent serious harm or death to a patient, a HUD may be administered without prior approval by an IRB. In such an emergency situation, the physician shall, within 5 days after the use of the device, provide written notification to the chairman of the IRB of such use. Such written notification shall include the identification of the patient involved, the date on which the device was used, and the reason for the use.

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§ 814.126 [Amended]

6. Amend § 814.126(b)(1)(iii) by removing the number “4,000” and adding in its place the number “8,000”.

Dated: June 1, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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